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Docket No. 02P-0462

December 18, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

To Whom It May Concern:

This comment refers to the Docket No. 02P-0462 – Petition for the Use of an Implied Nutrient Content Claim in the Brand Name “Carbolite”.

I would like to take this moment and voice my concerns regarding this petition. Having thoroughly read Carbolite’s petition, I feel compelled to raise a few salient points.

I. The Carbolite Trademark Is In Question.

Carbolite’s petition was submitted on October 4, 2002 and received by the FDA on October 7, 2002. The petition refers to “Carbolite®” as a registered trademark owned by Carbolite Foods, Inc. (pg. 1). According to the U.S. Patent and Trademark Office (USPTO), the federal registration symbol “®” may be used only when the trademark is actually registered in the U.S. Patent and Trademark Office. Even though an application is pending, the registration symbol may not be used before the mark has actually become registered. The facts are that the registration was not granted by the U.S. Patent and Trademark Office until November 26, 2002 (*Appendix A*).

In addition, Universal Nutrition has objected to the USPTO granting this trademark. We have submitted, through our legal counsel, our objections. We believe that our objections will succeed and the USPTO will withdraw the trademark from Carbolite Foods. There is sufficient legal precedence for this to occur, and the USPTO has withdrawn trademarks under similar circumstances in the past.

There is ongoing litigation between Universal Nutrition and Carbolite Foods involving the Carbolite trademark in the United States District Court, Southern District of Indiana, Indianapolis Division.

02P-0462

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II. Carbolite Foods is conflating a specific term, “sugar”, with a general term, “carbohydrate”, thus attempting to render both terms as interchangeable when they clearly are not.

It is very important to note that “sugar” related claims are what Carbolite Foods is petitioning for specifically, and not more general “carbohydrate” claims. On this subject, Carbolite Foods is very clear:

“Carbolite Foods, Inc. requests that FDA approve the Carbolite brand name.... formally authorizing its use in the labeling of foods qualifying for the claims ‘zero sugar’ and ‘reduced sugar,’ as defined under FDA regulations....” (pg. 4-5 of the petition).

And:

“The Carbolite brand name is used exclusively for ‘zero sugar’ and ‘reduced sugar’ foods that have been formulated with sugar alcohol sweeteners as alternatives to sugar-sweetened conventional foods for use in low carbohydrate weight loss diets, and other sugar-controlled diets. ... **Nonetheless, for the purposes of this petition, the expressed nutrient content claims, ‘zero sugar’ and ‘reduced sugar,’ as defined by FDA regulations, serve as the expressed nutrient content claims which function as regulatory benchmarks defining the Carbolite brand name.**” [emphasis ours] (pg. 9-10 of the petition).

It is also important to note that Carbolite Foods acknowledges that sugar alcohols used in their ‘zero sugar’ and ‘reduced sugar,’ products are still carbohydrates. Carbolite Foods has not disputed the FDA’s claim that sugar alcohols are not “carbohydrates”--merely that sugar alcohols are a different kind of carb.

While pointing out the differences between sugar carbs and non sugar carbs, Carbolite Foods admits that both are “separate types of ‘carbohydrates.’” Elsewhere they note that their products are designed not to reduce overall carbs, but specifically, “net effective carbs”. Carbolite Foods wants to use a product’s sugar levels as one of their benchmark criteria for the “Carbolite” Foods nutrient content claim. But sugar-free or reduced sugar foods are not necessarily foods that may be low or lite in carbs.

If, as Carbolite Foods claims, there are different kinds of carbs (e.g., fermentable carbs, net effective carbs, and non effective carbs), and if these carbs function in fundamentally different metabolic ways (i.e., blood sugar and insulin regulation), and if only certain types of the aforementioned carbs are relevant to Carbolite’s brand (i.e., non effective carbs), then Carbolite Foods certainly cannot and should not be able use a “one size fits all” approach with respect to the trade name, “Carbolite” and the nutrient content claim implied therein.

Not only is there no FDA definition for “lite” with respect to carbohydrates, I would argue that even if there was one existing, this definition would not apply for select carbohydrates,

but for ALL CARBOHYDRATES. In other words, Carbolite Foods could not pick and choose which carbs they would be referring to if they were to make an implied nutrient claim in the brand name, “Carbolite”. In essence, specific “zero” or “reduced” sugar claims are not tantamount to “Carbolite” in general.

Through faulty logic, Carbolite Foods is attempting to conflate “zero sugar” and “reduced sugar” with “carbohydrates” in general. They cannot argue for “zero sugar” or “reduced sugar” nutrient content claims in their petition, then argue that a general “Carbolite” brand name is suitable as an implied nutrient content claim. Once again, the terms, “sugar” and “carbs” ARE NOT interchangeable: while all sugars are carbs, NOT ALL CARBS ARE SUGARS.”

Yet this is precisely the kind of specious logic that Carbolite Foods is attempting to put forth. They want their petition approved for “zero sugar” and “reduced sugar” nutrient content claims, and then hope the FDA would turn a blind eye to the implied nutrient claim in the name “Carbolite” which refers generically to all carbs.

Carbolite Foods even acknowledges that the “carbo” portion of the word “carbolite” refers to carbohydrates in general, not sugars in particular. To dispel any potential ambiguity, Carbolite Foods writes: “... the ‘Carbo-’ term that is embedded in the Carbolite brand name constitutes an implied reference to ‘carbohydrate’” (pg. 9 of the petition). Thus Consumers may mistakenly believe that “carbolite” products are low in carbs, and not specifically sugars.

III. If granted, the petition would give Carbolite an unfair competitive advantage.

“Carbolite” is mislabeled according to the FDA because the name makes an unapproved nutrient content claim. If every other company needs to follow federal regulations CFR 21 Part 101.13 that address nutrient content claims, so should Carbolite Foods. We believe that if the FDA allows Carbolite Foods to use the term “Carbolite” on their entire product labeling, then Carbolite Foods will have an unfair competitive advantage over their competitors. Carbolite Foods will be the only company able to effectively call their products “low carb”. Since the FDA maintains that “low carb” is an unapproved nutrient content claim, then one company should not be able to state that their product is “low in carbs” or “lite in carbs” if other companies can not.

Universal Nutrition received a warning letter on this issue from the FDA, as did Carbolite Foods (*Appendix B*), and as did most companies who sold these types of foods. As a result of these warning letters and subsequent discussions with the FDA through an industry coalition, most companies changed their products’ names and labeling. Universal Nutrition changed our product from “Doctor’s LowCarb Diet” to “Doctor’s CarbRite Diet” to comply with FDA mandates. Again, Carbolite’s petition would give their products an unfair competitive advantage over other companies that have changed in compliance with the FDA.

Additionally, Carbolite Foods has filed for a trademark for the term “0 sugar carbs” with the USPTO (*Appendix C*). If their foods are labeled with the term “0 sugar carbs” as a condition to their use of the “Carbolite” claim, AND Carbolite Foods receives the trademark for “0 sugar carbs” then Carbolite Foods will now essentially corner the market for low carb claims on product labeling.

IV. Carbolite’s Fifth Amendment argument is flawed.

In Section E, pg.28-29 of the petition, Carbolite Foods argues that prohibiting the use of the Carbolite brand name would be detrimental to Carbolite Foods as they have been using the name for three years. Their argument is faulty, as Carbolite has been profiting from the use of an illegal name over the last three years while other companies have changed product and brand names to comply with the FDA. Carbolite could have changed their name a year and a half ago when they received their warning letter (*Appendix B*), or perhaps they should never have chosen a name in the first place that has an implied nutrient content claim. Carbolite Foods named their brand “Carbolite” precisely because it implies “low carbs”, and prohibiting its use is entirely fair and just if the FDA means to even-handedly enforce its warning letters and federal regulations.

V. Summary

The “Carbolite” trademark is in question and may be withdrawn. Carbolite Foods is in litigation concerning the trademark. The U.S. Patent and Trademark Office may withdraw the trademark from Carbolite Foods.

Carbolite Foods claims, there are different kinds of carbohydrates (net effective vs. non effective carbs) which affect blood sugar and insulin in different ways. Only a certain type of the aforementioned carbs are relevant to Carbolite’s brand, namely sugar alcohols or non effective carbs. And these certain non effective carbs refer directly to their petition for the nutrient content claims, “zero sugar” and “reduced sugar. Carbolite Foods admits that the “carbo-” portion of the name refers to “carbohydrates” in general, and not sugars in particular. Therefore Carbolite Foods cannot maintain a sound position when they petition the FDA for the trade name “Carbolite” while simultaneously positioning their food products with only sugar-specific nutrient content claims. Once again, name “Carbolite” refers generally to carbs, whereas Carbolite Foods, the company, is petitioning the FDA for sugar-specific nutrient content claims.

It appears that Carbolite Foods wants to elide the distinctions between sugar and carbohydrates. Carbolite Foods wants their cake and wants to be able to eat it to, so to speak. For the sake of the consumer, this should not be allowed to happen. It is potentially confusing and misleading. Consumers, based on the name “carbolite”, will invariably believe that the product they are purchasing are low in carbs, and not specifically sugars. I believe the FDA should take a strong position against Carbolite Foods, a position that the FDA has already forcefully made in their June 20, 2001 letter to Carbolite.

In the event the FDA does decide to grant Carbolite's petition then the FDA should allow all companies to use the terms "low carb", "low in carbohydrates", "lite in carbs", or labeling similar to the petitioner. To do otherwise would give an unfair competitive advantage to one company, Carbolite Foods. It would be analogous to allowing only one company to use the term "low fat" or "sugar free". There ought to be a level playing field so that consumers may receive consistent nutrient labeling. Allowing only one brand name (Carbolite in this case) to make the implied nutrient content claim of "low carb" would be deceptive to consumers as it would imply that Carbolite's products are uniquely low carb in comparison to other similar products.

Sincerely,

A handwritten signature in cursive script, appearing to read "Michael Rockoff".

Michael Rockoff